510(k) Summary of Safety and Effectiveness

JUL 2 4 2013

This 510(k) Summary of Safety and Effectiveness has been prepared in accordance with Code of Federal Regulations, Title 21 CFR, Part 807.92.

Date Prepared: April 25, 2013

Manufacturer: Philips Medical Systems Nederland B.V.
Veenpluis 4-6, 5684PC Best, The Netherlands
Establishment registration number: 3003768277

Contact Person (Owner): Dr. Jos van Vroonhoven
Phone: +31 40 2791111 Fax: +31 40 2769100

Proposed Device:

Trade name:	**XperGuide**
Classification regulation:	21 CFR, Part 892.1650
Classification name:	Image-intensified fluoroscopic x-ray system
Classification panel:	Radiology
Device classification:	Class II
Primary Product Code:	OWB (interventional X-ray system)
Secondary Product Code:	LLZ (radiological image processing system)

Primary Predicate Device 1:

Trade name:	Allura Xper FD20 X-Ray Imaging Systems
Manufacturer:	Philips Medical Systems Nederland B.V.
FDA clearance:	K033737 (December 9, 2003)
Classification regulation:	21 CFR, Part 892.1650
Classification name:	Image-intensified fluoroscopic x-ray system
Classification panel:	Radiology
Device classification:	Class II
Product Code:	OWB (interventional X-ray system)

Primary Predicate Device 2:

Trade name:	Allura Xper FD OR Table Series
Manufacturer:	Philips Medical Systems Nederland B.V.
FDA clearance:	K102005 (August 9, 2010)
Classification regulation:	21 CFR, Part 892.1650
Classification name:	Image-intensified fluoroscopic x-ray system
Classification panel:	Radiology
Device classification:	Class II
Product Code:	OWB (interventional X-ray system)

Note: The primary predicate devices 1 and 2 (Allura Xper FD20 X-Ray Imaging Systems and Allura Xper FD OR Table Series) are collectively referred to as "Philips Allura Xper FD X-Ray Imaging Systems" in this 510(k) Summary of Safety and Effectiveness.

Secondary Predicate Device:

Trade name:	Innova Vision Applications
Manufacturer:	GE Healthcare
FDA clearance:	K092639 (December 2, 2009)
Classification regulation:	21 CFR, Part 892.2050
Classification name:	Picture archiving and communications system
Classification panel:	Radiology
Device classification:	Class II
Product Code:	LLZ (radiological image processing system)

Device Description: XperGuide is a software medical device intended to assist the physician during percutaneous interventions by providing live 3D needle image guidance. XperGuide overlays live 2D fluoroscopic images on a 3D reconstruction of the anatomy. XperGuide provides real-time feedback on needle position with respect to the planned path.
In addition, the XperGuide has an ablation option, which visualizes the combined ablation zone of multiple planned needles.

Intended Use: XperGuide is an extension of XperCT, which assists in percutaneous interventions, such as biopsies, drainages, etc., by providing needle path planning and image guidance by superimposing live fluoroscopic images of the needle on a cross sectional image of the targeted anatomy.
The XperGuide Ablation option assists with planning the position of multiple needles by visualizing the ablation coverage of the lesion.

Technology: XperGuide is provided on the independent hosting software functionality platform of the currently marketed Philips Interventional Workspot (K121296, January 2, 2013). Live 2D fluoroscopy images and exam data are transmitted from the currently marketed and predicate Philips Allura Xper FD X-Ray Imaging Systems (K033737, K102005) to Interventional Workspot through a dedicated real-time link and are overlaid on a slab of the 3D planning volume, either created by the currently marketed XperCT (K060749, April 4, 2006) or from a previously acquired CT or MR data set. Live 2D/3D fluoroscopic overlay runs, together with planning information, snapshots and movies, can be stored in a local database for use in XperGuide and can be reviewed at any time.
Live 2D/3D overlay images and the XperGuide user interface are shown on monitors in the control room and in the exam room with use of a video splitter. XperGuide can be operated from the control room (via keyboard and mouse) as well as in the exam room (via the Xper module of the currently marketed and predicate Philips Allura Xper FD X-Ray Imaging Systems).

The technology utilized in both XperGuide and the currently marketed and predicate Innova Vision Applications with TrackVision option (GE Healthcare, K092639) includes:

- Execution on and connection to an independent software hosting platform;
- Transmission of live 2D fluoroscopy images and exam data from a digital X-ray imaging system to the software hosting platform (workstation) through a dedicated real-time link;
- Loading of previously acquired 3D data sets from the software hosting platform (workstation);
- Fusion or superimposing live 2D fluoroscopy images on top of selected 3D cross-sectional images of the targeted anatomy;
- Storage of live 2D/3D overlay runs and of fused photos and video clips in a local database;
- Display of overlay images and user interface in the control room and in the exam room;
- Operation of the software medical device from the control room and in the exam room.

Based on the information provided above, XperGuide is considered substantially equivalent to the currently marketed and predicate Innova Vision Applications with TrackVision option (GE Healthcare, K092639) in terms of technology.

Non-clinical Performance Data:

The proposed XperGuide software medical device complies with the following international FDA-recognized consensus standards:

- IEC 62304 Medical device software – Software life cycle processes (2006);
- IEC 62366 Application of usability engineering to medical devices (2007);
- ISO 14971 Application of risk management to medical devices (2007).

Non-clinical verification and validation tests have been performed with regards to the requirement specifications and the risk management results. These tests specifically include software verification and validation conformance testing. The test results demonstrate that XperGuide meets the acceptance criteria, and is adequate for its intended use. Therefore, the XperGuide software medical device is substantially equivalent to the currently marketed and predicate Innova Vision Applications with TrackVision option (GE Healthcare, K092639) in terms of safety and effectiveness.

Conclusion:

XperGuide is substantially equivalent to the currently marketed and predicate Innova Vision Applications with TrackVision option (GE Healthcare, K092639) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 24, 2013

Philips Medical Systems Nederland B.V.
% Dr. Jos van Vroonhoven
Standardization Manager
Veenpluis 4-6 5684 PC Best
NETHERLANDS

Re: K131263
Trade/Device Name: XperGuide
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ
Dated: April 25, 2013
Received: May 03, 2013

Dear Dr. Vroonhoven:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

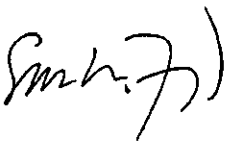
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131263

Device Name: XperGuide

Indications for Use:

XperGuide is an extension of XperCT, which assists in percutaneous interventions, such as biopsies, drainages, etc., by providing needle path planning and image guidance by superimposing live fluoroscopic images of the needle on a cross sectional image of the targeted anatomy.

The **XperGuide** Ablation option assists with planning the position of multiple needles by visualizing the ablation coverage of the lesion.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131263